K092727

H100B Pulse Oximeter 510(k) Submission DEC - 3 2009
Section 1

510（K）Summary of Safety and Effectiveness

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

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Proprietary Name: H100B Pulse Oximeter

Classification Name: 21 CFR 870.2700 Oximeter

Product code: DQA

Classification: Class II

Predicate Devices: PM 60 Pulse Oximeter K072581
Shenzhen Mindray Bio-medical Electronics Co., LTD

Device Description: H100B Pulse Oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation (SpO2) and pulse rate of single adult, pediatric or neonate patient in hospitals, intra-hospital transport and hospital type facilities. The sampled signal from finger sensor is processed in the main unit and transferred into electronic signal to display the SpO2 value, pulse rate value on the LCD at the form of numeral, plethysmogram, bar graph and waveform. Data management software (Oximeter Viewer) can transferred stored data into PC for storage, review and printing.

The subject device is powered by 4 pieces 1.5V AA batteries or 4 pieces 1.2V Ni-H rechargeable AA batteries. Alarm capability including audio alarm and indicator is provided when the SpO2 value is lower than the limit setup or some technical reason.

Comparison with predicate device

	Subject device	Predicated device
Monitoring functions	H100B Pulse Oximeter	PM60 Pulse Oximeter
SpO2	yes	yes
Pulse Rate	yes	yes
Alarm feature	yes	yes
Data management software	yes	yes

Intended Use: The H100B Pulse oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation (SpO2) and pulse rate of single adult, pediatric or neonate patient in hospitals, intra-hospital transport and hospital type facilities.

Test Summary: The following quality assurance measures were applied to the development of the H100B Pulse Oximeter:

- Software testing
- Safety testing
- Risk analysis
- Final validation

Conclusion: Verification and validation testing was done on the H100B Pulse Oximeter. This premarket notification submission demonstrates that H100B Pulse Oximeter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC - 3 2009

Edan Instruments, Incorporated
C/O Mr. Li Fu
Consultant
Shanghai MidLink Business Consulting Company, Limited
Suite 8D, No. 19, Lane 999, Zhongshan Road (S-2)
Shanghai, 200030, China

Re: K092727
Trade/Device Name: H100B Pulse Oximeter
Regulation Number: 21CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 31, 2009
Received: September 4, 2009

Dear Mr. Fu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication for Use

510(k) Number (if known):

Device Name: H100B Pulse Oximeter

The H100B Pulse oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation (SpO2) and pulse rate of single adult, pediatric or neonate patient in hospitals, intra-hospital transport and hospital type facilities.

Prescription Use ___X___ Or Over the Counter Use _____.

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

10(k) Number: K092727